

FERRITIN SYSTEM PACK

(Latex Turbidimetry Method)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 ,
Beaconnic chem 200, Beaconnic B200, Beaconnic analyzer 120,
Bonavera chem 100 (Fully Auto Biochemistry Analyzer)



| Code | Product Name | Pack Size |
|--------|----------------------|----------------|
| BA237 | Ferritin System Pack | 1x20 + 1x5 ml |
| BA237A | Ferritin System Pack | 2x20 + 2x5 ml |
| BA237B | Ferritin System Pack | 1x40 + 1x10 ml |
| BA237C | Ferritin System Pack | 2x40 + 2x10 ml |

INTENDED USE

For the quantitative determination ferritin human serum or plasma.

PRINCIPLE

Latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration.

CLINICAL SIGNIFICANCE

Serum ferritin concentration usually reflects body iron stores and is considered one of the most reliable indicators of iron status of patients. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk.

REAGENT COMPOSITION

| | |
|--|--|
| Reagent 1 : Diluent | Tris Buffer 20 mmol/L, pH 8.2. Preservative. |
| Reagent 2 : Latex | Latex particles coated with rabbit IgG anti-human ferritin pH 8.2. Preservative. |
| Reagent 3 : Ultima Ferritin Calibrator | Calibrator. Ferritin concentration is stated on the vial. |

PREPARATION

Ferritin Calibrator: Reconstitute (→) with 3.0 mL of distilled water. Mix gently and incubate at room temperature for about 10 minutes before testing.

STABILITY AND STORAGE

All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2-+8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND HANDLING

- Fresh serum. Stable 7 days at +2-+8°C or 3 months at -20°C. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

CALIBRATION

The calibration is stable for at least 1 month.

Recalibrate when control results are out of specified values; when using a different lot of reagent and when the instrument is adjusted.

Calibration curve: Prepare the following dilutions of the Ferritin Calibrator using NaCl 9 g/L. To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table:

| Calibration dilution | 1 | 2 | 3 | 4 | 5 | 6 |
|---------------------------------|-----|------|-----|-----|-----|-----|
| Ultima ferritin calibrator (μL) | — | 25 | 50 | 100 | 200 | 400 |
| NaCl 9 g/L (μL) | 400 | 375 | 350 | 300 | 200 | — |
| Dilution Factor | 0 | 1/16 | 1/8 | 1/4 | 1/2 | 1,0 |

CALCULATIONS

Calculate the absorbance difference ($A_2 - A_1$) of each point of the calibration curve and plot the values obtained against the Ferritin concentration of each calibrator dilution. Ferritin concentration in the sample is calculated by interpolation of its ($A_2 - A_1$) in the calibration curve.

QUALITY CONTROL:

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUES

Men: 30-220 μg/L

Women: 20-110 μg/L

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: Up to 600 μg/L. Samples with higher values should be diluted 1/5 in NaCl 9 g/L and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

Detection limit: 5.04 µg/L.

Quantification limit: Values under 6.6 µg/L may give non-reproducible results.

Prozone effect: No prozone effect was detected at least up to 9000 µg/L.

Precision:

| | Intra-assay (n=20) | | Inter-assay (n=20) |
|-------------|--------------------|--------|--------------------|
| mean (µg/L) | 33.55 | 112.80 | 286.8 |
| SD | 1.00 | 0.89 | 1.66 |
| CV (%) | 2.98 | 0.79 | 0.58 |

Method comparison: The reagent was compared to another commercially available Ferritin reagent by testing 20 samples (male and female) The coefficient of correlation (r) was 0.999 and the equation $y = 1.0052x - 0.1473$

Performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirubin (40 mg/dL), hemoglobin (5 g/L), γ and rheumatoid factor (750 IU/ml), do not interfere. Lipids (≥ 2.5 g/L) do interfere. Other substances may interfere.

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious. MSDS will be provided on request.

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

| | |
|------------------------|------------|
| Test Name | FERRITIN |
| Full Name | FERRITIN |
| Pri Wave | 546 nm |
| Sec Wave | - |
| Assay/point | Fixed Time |
| Start | 18 |
| End | 34 |
| Decimal | 2 |
| Unit | µg/L |
| Linearity Range Low | 5.04 |
| Linearity Range High | 600 |
| Sample Volume | 18 µl |
| Reagent 1 (R1) Volume | 160 µl |
| Reagent 2 (R2) Volume | 40 µl |
| Substrate Depleted | - |
| Linearity | 600 µg/l |
| Out Of Linearity Range | - |
| Calibration Type | Spline |
| Points | 6 |

| | |
|---------------------|------------------------------|
| Blank Type | Reagent |
| Concentration Blank | 0.00 |
| Concentration Std | Refer calibrator value sheet |









NOTE

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

BIBLIOGRAPHY

1. Knovich MA et al., Blood Rev. 2009 23(3)-95-104
2. Mazza J et al. Can Med Assoc J 1978; 119: 884-886
3. Rodriguez Perez J et al. Revista Clinica Espafiola 1980:

Symbols Used On Labels

| | | | |
|---|-------------------------|---|----------------------|
|  | Catalogue Number |  | Manufacturer |
|  | See Instruction for Use |  | Lot Number |
|  | Content |  | Storage Temperature |
|  | Expiry Date |  | In Vitro Diagnostics |

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